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Food and Drug Administration
Washington DC 20204

WARNING LETTER
ONPLDS-03-00

JUL 18 2000

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

David McCabe
President and CEO
Worldwide Sport Nutritional Supplements, Inc.
10540 72nd Street
Largo, Florida 33777

Dear Mr. McCabe:

The Food and Drug Administration (FDA) has reviewed labels for some of your products including the labels for Pure Protein High Protein/Low Carb Meal Replacement Bar, BURN-IT High Protein/Low Carb Low Fat Burn-It Bar, and Chocolate Covered Coconut Pure Protein Cookie. Our review reveals that these labels cause the above products to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), and food label requirements as follows:

Pure Protein High Protein/Low Carb Meal Replacement Bar

This product is misbranded because the label bears the claim "LOW CARB" which is a nutrient content claim that is not authorized by regulation or the Act (21 U.S.C. 343(r)(1)(A)).

The product is also misbranded because the label states that this bar is high in protein but fails to declare in the nutrition information the corrected amount of protein per serving calculated as a percentage of the Daily Reference Value (DRV) and expressed as a percentage of the Daily Value (21 U.S.C. 343(q) and 21 CFR 101.9(c)(7)(i)).

The product is further misbranded because the label bears the statement "Glycerine is not a carbohydrate but has a caloric value of 4.32 per gram" (21 U.S.C. 343(a)). Glycerine is a carbohydrate. In addition, it is not clear whether glycerine is included in your declaration of "total carbohydrates" for this food. We advise that glycerine must be included in the value declared for "Total Carbohydrates."

The declaration of the ingredient “hydrolyzed protein” does not include the food source of the protein.

The product bears the claim “Fortified with Vitamins and Minerals.” This claim should reference either the number of vitamins and minerals or the specific vitamins and minerals that are the subject of the claim. In addition, “fortified” triggers the requirements of 21 CFR 101.54(e).

BURN-IT High Protein/Low Carb Low Fat Burn-It Bar

This product is misbranded because the label bears the claim “LOW CARB” which is a nutrient content claim that is not authorized by regulation or the Act (21 U.S.C. 343(r)(1)(A)).

The product is also misbranded because the label states that this bar is high in protein but fails to declare in the nutrition label the corrected amount of protein per serving calculated as a percentage of the Daily Reference Value (DRV) and expressed as a percentage of the Daily Value (21 U.S.C. 343(q) and 21 CFR 101.9(c)(7)(i)). In addition, Hydroxycitric Acid 50%, L- Carnitine, and Chromium Polynicotinate must not be declared, as such, in the nutrition label format. Chromium must be declared in the nutrition format as percent of Daily Value and the amounts of the other substances may be declared on the label outside the nutrition format.

The product is **further** misbranded because the label bears the statement “Glycerine is not a carbohydrate but has a caloric value of 4.32 per gram” (21 U.S.C. 343(a)). Glycerine is a carbohydrate. In addition, it is not clear whether glycerine is included in your declaration of “total carbohydrates” for this food. We advise that glycerine must be included in the value declared for “Total Carbohydrates.”

The claim “Low Fat” is not accompanied by the required statement describing the basis for the claim (21 CFR 101.13(p) and 21 CFR 101.12(g)). The labeled serving size (one 50 gram bar) differs from the reference amount customarily consumed (40 grams) and the product appears to meet the criterion for “low fat” only on a basis of the reference amount. Therefore, the claim “low fat” must be followed by a statement that sets forth the basis on which the claim is made (e.g., Low fat, 3 grams or less fat per 40 grams (1.4oz)).

The declaration of the ingredient “hydrolyzed protein” does not include the food source of the protein.

Chocolate Covered Coconut Pure Protein Cookie

This product is misbranded because the label bears the claim “LOW CARB” which is a nutrient content claim that is not authorized by regulation or the Act (21 U.S.C. 343(r)(1)(A)).

The product is also misbranded because the label states that this product is high in protein but fails to declare, in the nutrition label, the corrected amount of protein per serving calculated as a percentage of the Daily Reference Value (DRV) and expressed as a percentage of the Daily Value (21 U.S.C. 343(q) and 21 CFR 101.9(c)(7)(i)).

The product is further misbranded because the label bears the statement “Glycerine is not a carbohydrate but has a caloric value of 4.32 per gram” (21 U.S.C. 343(a)). Glycerine is a carbohydrate. In addition, it is not clear whether glycerine is included in your declaration of “total carbohydrates” for this food. We advise that glycerine must be included in the value declared for “Total Carbohydrates.”

The declaration of the ingredient “hydrolyzed protein” does not include the food source of the protein.

The above violations are not meant to be an all inclusive list of deficiencies on your labels. It is your responsibility to assure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct ~~these~~ deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken or plan to take to correct the noted violations. Copies of revised labels for the products should also be submitted. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

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You should direct your written reply to me at: the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810), 200 C Street, S.W., Washington, D.C. 20204.

Sincerely yours,

/s/

John B. Foret
Director
Division of Compliance
and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition